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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,499	10/14/2003	Yi-Xiong Zhou	BDI004-CIP	3529

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EXAMINER	
MILLER, MARINA I	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/686,499	ZHOU, YI-XIONG	
	Examiner	Art Unit	
	Marina Miller	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-62* is/are rejected.

7)☒ Claim(s) *9 and 29* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election of species the classification of contamination in the reply filed on 7/18/2006 is acknowledged. Upon further review, however, the examiner has determined that classifying a signal, a background, a contamination are not different species, but one process of classifying pixels as a signal, a background, a contamination. For this reason, the election of species requirement is hereby withdrawn and all claims are rejoined.

Claims 1-62 are pending.

Claims 1-62 are presently under examination.

Priority

It is noted that this application appears to claim subject matter disclosed in prior Application No. 09/416,576 (U.S. Patent 6,633,659), filed 10/12/1999. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after

November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required.

Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Claim Objections

Claims 9 and 29 objected to because of the following informalities: claims 9 and 29 recite in lines 7 and 9, respectively, "a set histogram bins." For the purpose of the examination, examiner interprets this to be a typographical error, and claims 9 and 29 are treated as reciting "a set of histogram bins."

Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 21-22 and 24-62 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 21-22 and 24-40 are directed to a method for assessing chemical materials manifested as an array of signals comprising steps of detecting a center pixel and an approximate radius of a signal of a chemical material; segmenting the signal; and assessing the segmented signal by classifying pixels as tentative signals and tentative background signals, determining major modes of pixels, and using pixel intensities to reclassify tentative signal and background pixels. Claims 52-62 are directed to a method of segmenting a signal of a chemical material comprising steps of detecting a center pixel and an approximate radius of a signal, classifying

pixels, determining major modes of pixels, and using pixel intensities to reclassify tentative signal and background pixels. However, not all processes are statutory under 35 U.S.C. 101. *See Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility.* 1300 O.G. 4, on 22 November 2005 (published at the USPTO web site http://www.uspto.gov/web/patents'patog/week47/OG/TOC.htm). To satisfy 101 requirements, the claim must be for a practical application, which can be met if the claimed invention "transforms" an article or physical object to a different state or thing OR the claimed invention otherwise produces a useful, concrete, and tangible result. If claims are directed to abstract ideas (such as mathematical algorithms), natural phenomena, and laws of nature, the claims must be considered as a whole for determining whether an abstract ideas, natural phenomena, or laws of nature has a particular application.

In the instant case, the claimed method steps describe nothing more than the manipulation of basic mathematical constructs, the paradigmatic 'abstract idea.' Specifically, the claimed method recites mathematical and/or statistical manipulations with hybridization information (signals, pixels). The claimed method does not transform or reduce an article or a physical object (*e.g.*, hybridization signals) to a different stage or thing because the "result" of the method (*i.e.*, assessed segmented signals) is merely data (hybridization information) and is not equivalent to physical transformation. The claims do not recite tangible expression (*i.e.*, real-world result) of the assessed signals, nor any recitation of an actual (*i.e.*, concrete) result in a form useful to one skilled in the art. Thus, the method does not recite steps of producing something that is concrete, useful, and tangible, and is not statutory.

Claims 41-51 are directed to a computer program including an implementation of the method of claim 1 stored in a computer-readable medium. A computer readable medium may be a carrier wave, which is not a physical object. Thus, the claimed computer readable medium of claims 41-51 is not necessarily a physical "product," as it may be a carrier wave, and therefore is non-statutory.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 4-20 recite a processor for segmenting. The limitation makes claims vague and indefinite because it is not clear whether the processor is intended to physically segment and reclassify (*e.g.*, the way a laser assisted cell counter can physically classify and gate particles according to the signals generated by the particles) OR whether the processor is intended to comprise INSTRUCTIONS for performing the recited steps. For the purposes of further examination, the claims are interpreted to be directed to a processor comprising instructions for performing the steps recited in claims 1 and 4-20. As the intended limitation is not clear, claims 1-20 are indefinite.

Claims 1, 21, 41, and 51 recite the limitation "the approximate radius of the center-representing pixel." The antecedent basis of the limitation is not clear because in the preceding parts the claims recite "a center-representing pixel" and "an approximate radius of a signal" but

not "an approximate radius of a center-representing pixel." As the intended limitation is not clear, claims 1-62 are indefinite.

Claims 1 and 21 recite the limitation "assessing" an image. The limitation makes the claims vague and indefinite because criteria, parameters, or algorithms of "assessing" are not clear, *e.g.*, what chemical material and a segmented image are assessed for, and neither the specification nor the claims defines the limitation. As the intended limitation is not clear, claims 1-40 are indefinite.

Claims 1, 21, 41, and 52 recite the limitation "using pixel intensity relative to the signal major mode ... to reclassify ... pixels." The limitation makes the claims vague and indefinite because specific steps of "using" intensity are not clear. Further, the parameters of "relatedness" of intensity and a signal major mode are not clear.

It is also unclear whether the term "to reclassify" is intended to be an active, positive method step or merely an intended result of the method.

As the intended limitation is not clear, claims 1-62 are indefinite.

Claims 7, 27, and 56 recite in lines 6-9 the limitation "the homogeneous region" of pixels. The antecedent basis of the limitation is not clear because claims 7, 27, and 56 recite in the proceeding part only "a region" of pixels, but do not recite "a homogeneous region." As the intended limitation is not clear, claims 7-8 and 27-28 are indefinite.

Claim 9 recites in lines 1-2 the limitation "determining *a major mode* for the tentative signal pixels and *a major mode* for the tentative background pixels." Claim 29 recite the same

limitation. Claim 9 depends from claim 1, which recites in lines 11-12 "determining *a signal major mode* for the tentative signal pixels and a *background major mode* for the tentative background pixels." Claim 29 depends from claim 21, which also recites "determining *a signal major mode* for the tentative signal pixels and a *background major mode* for the tentative background pixels." It is not clear whether two major modes recited in claims 9 and 29 are the same or different from a signal and background major modes recited in claims 1 and 21. As the intended limitation is not clear, claims 9-10 and 29-30 are indefinite.

Claims 9 and 29 recites in lines 16 and 18, respectively, the limitation "the major mode for each histogram." Claims 9 and 29 also recite in lines 1-2 "a major mode for the tentative signal pixels and a major mode for the tentative background pixels." Claims 48 and 59 also recite "the major mode for each histogram." Claims 48 and 59 depend from claim 47 and 58, which recite "a major mode for the tentative signal pixels and a major mode for the tentative background pixels." It is not clear whether "the major mode" for a histogram is the same or different from "a major mode for" a signal and background pixels. As the intended limitation is not clear, claims 9-10 and 48-49 are indefinite.

Claims 12, 32, 51, and 62 recite the limitation "determining a measure of performance at detecting in the digital image a ... pixel." It is not clear what "a measure of performance" is intended to mean. It is further not clear whether some performance is measured while performing a step of "detecting a pixel and a radius" OR "performance" *is* detecting a pixel, which pixel is measured. Claims 13-20 and 33-40 depend from claims 12 and 32 and also recite the limitation "the measure of performance." As the intended limitation is not clear, claims 12-20, 32-40, 51, and 62 are indefinite.

Claims 12, 32, 51, and 62 recite the limitations "a center-representing pixel," "an approximate radius," "a signal", and "a chemical material." Claims 12, 32, 51, and 62 depend from claims 1, 21,41, and 52, respectively, which also recite "a center-representing pixel," "an approximate radius," "a signal", and "a chemical material." It is not clear whether the above-recited limitation of claims 12, 32, 51, and 62 are intended to be the same or different from those recited in claims 1, 21,41, and 52. As the intended limitation is not clear, claims 12-20, 32-40, 51, and 62 are indefinite.

Claims 1, 12, 21, 32, 41, and 51 recite a step of "segmenting a signal" and "assessing the segmented signal." First, is in not clear whether "segmenting a signal" is intended to mean, for example, classifying pixels as a signal and a background; discarding a signal if it is below some predetermined threshold; splitting a signal in narrower "bands", *etc.*

Second, the claims also recite that the step of segmenting comprises classifying pixels, determining major modes of pixels, and using pixel intensity to reclassify pixels. The result of the step of segmenting is "reclassified signal and background pixels." Thus, it is not clear what is intended to be assessed, because it is not clear whether "reclassified pixels" *are* a segmented signal.

As the intended limitation is not clear, claims 1-62 are indefinite.

Claims 1, 21, and 41 recite in the preamble "assessing chemical material manifested as an array of signals." The steps further recite "assessing the segmented signals." It is not clear whether the goal of the method is to assess "chemical material," *e.g.*, what chemicals are disposed on an array or for what drug the array is specific, OR to assess whether a signal

produced by a chemical array is, for example, a real signal or just a background noise. If the former, then the relationships between the preamble and the method steps are not clear. As the intended limitation is not clear, claims 1-51 are indefinite.

Claims 12, 32, and 51 recite the limitation "segmenting the signal, and calculating a measure of the segmented signal." Claims 12, 32, and 51 depend from claim 1, 21, and 41, which also recite "segmenting the signal, and calculating a measure of the segmented signal." Thus, it is not clear what further limitation of claims 1, 21, and 41 is intended by reciting the steps which have been already recited. As the intended limitation is not clear, claims 12-20, 32-40, and 51 are indefinite.

Claim 62 recites "[t]he method of claim 52, further comprising the step of ... *segmenting*." Claim 62 depends from claim 52 which is directed to a method for *segmenting* a signal comprising steps of classifying, determining, and using. It is not clear whether the step of "segmenting" recited in claim 62 is intended to be an additional step to the steps recited in claim 52 or is intended to substitute the steps recited in claim 52. (*See*, for example, claims 1, 21, and 41 reciting a step of segmenting *comprising* steps classifying, determining, and using.) As the intended limitation is not clear, claim 62 is indefinite.

Double Patenting

Statutory

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-62 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-62 of prior U.S. Patent No. 6,633,659. This is a double patenting rejection.

Instant claims 1-62 directed to a method, a system, and a computer readable medium for assessing chemical material and segmenting a signal are identical to claims 1-62 of U.S. Patent No. 6,633,659.

Non-Statutory

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claims are not patentably distinct from the reference claims because the examined claims are either anticipated by, or would have been obvious over the reference claims. *See, e.g., In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Groups of claims (1-3), 11, 21, (22-23), 31, 41, and 50 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims (1-3), 6, 7, 8, 10, 11, and 13 of U.S. Patent 6,731,781 ('781).

Instant claim 1 directed to a system for assessing chemical material comprising a memory and a processor for assessing an image, detecting a center and a radius, segmenting the signal, and calculating a measure of the segmented signal. Claim 2 limits the system of claim 1 to a further comprise a scanner. Claim 3 limits the system of claim 1 to a further comprise an arrayer. Claim 11 further limits claim 1 to a nucleic acid array.

Claim 1 of '781 is directed to a system for assessing chemical material comprising a memory and a processor for assessing an image, identifying each of plurality of sub-grids in the image, detecting a center and a radius in each sub-grid, segmenting, and calculating a measure of the segmented signal. Claim 2 limits the system of claim 1 to a further comprise a scanner. Claim 3 limits the system of claim 1 to a further comprise an arrayer. Claim 6 further limits claim 1 to a nucleic acid array.

Instant claim 21 is directed to a method of assessing chemical material comprising steps of detecting a center and a radius, segmenting the signal, and assessing the segmented signal. Claims 22-23 further comprise steps of generating a digital image and depositing the chemical material on a slide, respectively. Claim 31 further limits claim 21 to a nucleic acid array.

Claim 7 of '781 is directed to a method for assessing chemical material comprising steps of identifying each of plurality of sub-grids in an image, detecting a center and a radius in each sub-grid, segmenting, and calculating a measure of the segmented signal. Claim 8 further limits claim 7 to comprise steps of generating a digital signal and depositing the chemical material on a slide. Claim 10 further limits claim 7 to a nucleic acid array.

Instant claim 41 is directed to a computer-readable medium for assessing chemical material performing steps of detecting a center and a radius, segmenting the signal, and

calculating a measure of the segmented signal. Claim 50 further limits claim 41 to a nucleic acid array.

Claims (1-3), 6, 7, 8, 10, 11, and 13 of '781 discloses the same system, method and computer-readable medium as those recited in instant claims (1-3), 11, 21, (22-23), 31, 41, and 50, wherein assessing also comprises a step of identifying each of plurality of sub-grids in the image; therefore claims (1-3), 6, 7, 8, 10, 11, and 13 of '781 anticipate claims (1-3), 11, 21, (22-23), 31, 41, and 50 in the instant application.

Claims 1 and 21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 76 of U.S. Patent 7,099,502 ('502).

Instant claim 1 is directed to a system for performing a method for assessing chemical material comprising a memory and a processor performing steps of detecting a center and a radius, segmenting the signal, and calculating a measure of the segmented signal.

Instant claim 21 is directed to the method for assessing chemical material.

Claim 76 is directed to a system for assessing chemical material comprising a memory and a processor for performing steps of identifying characteristics of a grid from an image, detecting a center and a radius, segmenting a signal, and calculating a measure of the segmented signal.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to use the system of claim 76 of '502 to perform the method of assessing chemical material, where the motivation would have been to conduct complicated and voluminous mathematical and statistical operations on a computer.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Miller whose telephone number is (571)272-6101. The examiner can normally be reached on 8-6, M-Thu.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, Ph. D. can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marina Miller
Examiner
Art Unit 1631

MM

MARJORIE A. MORAN
PRIMARY EXAMINER

Marjorie A. Moran
9/18/06